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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,096	01/08/2001	Lloyd G. Mitchell	A31304-B-A-B	5647

21003 7590 06/03/2003

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NEW YORK, NY 10112

EXAMINER

EPDS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/756,096

Applicant(s)

MITCHELL ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18 drawn to nucleic acid molecules comprising, for example, two or more target binding domains and a 3' splice region comprising a branch point, a pyrimidine tract and a 3' splice acceptor site and a 5' splice donor site, vectors, compositions and cells comprising a nucleic acid molecule, classified in class 435, subclass 325.
  - II. Claims 19-25 drawn to a method of producing chimeric RNA molecule in a cell, classified in class 435, and subclass 6.
  - III. Claims 26-44 and 52 drawn to nucleic acid molecules comprising, for example, one or more target binding domains, and a 5' splice donor site, vectors, compositions and cells comprising a nucleic acid molecule, classified in class 435, subclass 325.
  - IV. Claims 45-51 drawn to a method of producing chimeric RNA molecule in a cell, classified in class 435, and subclass 6.
  - V. Claim 53 drawn to a nucleic acid molecule wherein said nucleic acid molecule is CFTR PTM24, classified in class 536, subclass 23.1
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as product and process of use. Inventions III and IV, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced

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with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecules, vectors and cells recited in inventions I and III can be used for a materially different method other than the methods set forth in Inventions II and IV. For example the nucleic acid molecules of Invention I and III can be used for producing proteins encoded by the trans-spliced gene products encoded by the nucleic acid molecules comprised within the respective nucleic acid molecules according to Inventions I and III.

4. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, although the claimed methods comprise similar objectives, these methods comprise the use of chemically distinct nucleic acid molecules, which comprise distinct structures, and possess different modes of operation.

5. Invention V is unrelated to invention II and IV since the nucleic acid molecule of invention V is not disclosed as being capable of use in the methods according to inventions II and IV. Inventions II and IV require the use of nucleic acid molecules comprising a structure according to either Invention I or III. The nucleic acid molecule according to Invention V is structurally distinct from both Invention I and III, therefore it is not immediately apparent that the nucleic acid molecules of Inventions I and III can be substituted by Invention V to be used in the methods set forth in Inventions II and IV.

6. Inventions I, III and V are unrelated since they are drawn to chemically and structurally distinct nucleic acid molecules. The nucleic acid molecules of Inventions I and III represent

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trans-splicing cassettes that are useful for trans-splicing a gene of interest. However, Inventions I and III comprise different splicing components, and therefore possess different modes of operation. The nucleic acid molecule of Invention V represents a gene that encodes CFTR PTM24 and does not represent a trans-splicing cassette suitable for cloning a gene of interest as inventions III and I.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. A telephone call was made to Carmella Stephens on 5-28-03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

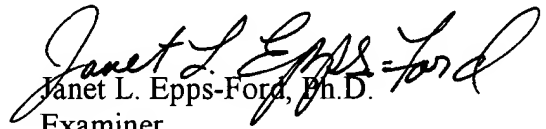
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
May 28, 2003